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APPLICATION NO.	PPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,099 11/29/2001		/29/2001	Mary Mowrey-McKee	LP/V-31594/A	3645
31781	7590	07/01/2004		EXAMINER	
CIBA VISI			YU, GINA C		
PATENT DI		NT PARKWAY	ART UNIT	PAPER NUMBER	
DULUTH,				1617	
				DATE MAIL ED: 07/01/200	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/997,099	MOWREY-MCKEE ET AL.					
Office Action Summary	Examiner	Art Unit					
	Gina C. Yu	1617					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPITHE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statu  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	I. 1.136(a). In no event, however, may a reply be to ply within the statutory minimum of thirty (30) day of the will expire SIX (6) MONTHS from the cause the application to become ABANDON.	timely filed  ays will be considered timely.  m the mailing date of this communication.  JED (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on <u>29 March 2004</u> .							
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) 1-18 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-18 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examin 10) The drawing(s) filed on is/are: a) ac Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	ccepted or b) objected to by the edrawing(s) be held in abeyance. Section is required if the drawing(s) is o	ee 37 CFR 1.85(a). bjected to. See 37 CFR 1.121(d).					
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)	A) 🖂 Interview Commen	(DTO 440)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date	4) Interview Summan Paper No(s)/Mail D 3) 5) Notice of Informal I 6) Other:						

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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2004 has been entered.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuzuki et al. (US 6417144 B2) ("Tsuzuki").

Tsuzuki discloses a contact lens solution comprising 0.05 –01 w/v % by weight of CAE (N-coconut oil fatty acid acyl L-arginine ethyl-DL-pyrrolidone carboxylate, an amino acid type cationic surfactant), Poloxamer 407 (surfactant), 0.1 w/v % of Bis-Tris EDTA (a chelating agent), NaCl (a tonicity agent), and hydroxypropylmethyl cellulose (a thickener). See Tables 1 and 2; instant claims 1, 2, 5, 10-17. The reference teaches

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that the amino acid type cationic surfactant has disinfection power in addition to the cleaning power, which meets the microbicide limitation of instant claim 1. See Tsuzuki, col. 7, lines 9-20. The reference also teaches that the pH of the solutions are 7.3. See col. 7, lines 36-42; instant claims.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 6, 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuzuki et al. (US 6417144) ("Tsuzuki") as applied to claims 1-5, 8, 10-18 above under § 102 (e).

While Tsuzuki fails to teach formulations comprising polyhexamethylene biguanide, the reference suggests using the polymer as a disinfectant. See col. 6, lines 48 – col. 7, line 6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the formulations in Tsuzuki by substituting the cationic polymer therein with polyhexamethylene biguanide as suggested by the reference because of an expectation of successfully producing a contact lens solution with cleaning and disinfecting properties.

## Response to Arguments

Applicant's arguments filed March 29, 2004 have been fully considered but they are not persuasive.

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Applicants assert that the present invention claims priority over the cited reference. In fact, Tsuzuki et al. (US 6417144 B2) has the effective filing date of June 14, 2000, which is prior to the November 29, 2000 date of the present application.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu Patent Examiner

> SREENI PADMANABHAN SUBERVISORY PATENT EXAMINER